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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/763,861

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Scott E. Jahns

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EXAMINER

BACHMAN, LINDSEY MICHELE

ART UNIT	PAPER NUMBER
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3734

MAIL DATE	DELIVERY MODE
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08/22/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/763,861

Applicant(s)

JAHNS ET AL.

Examiner

Lindsey Bachman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18, 20-29 and 48-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-18, 20-29 and 48-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to Applicant's amendment filed on 29 May 2007.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56.

The correct statement should read "I acknowledge the duty to disclose information which is material to patentability of this application in accordance with Title 37, Code of Federal Regulations Section 1.56."

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 1-7, 9, and 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over LeMole'369 in view of Nobles et al. (US Patent 6,171,319) in further view of Burbank, et al. (US Patent 6,689,071).

LeMole'369 teaches a device that creates an opening in a blood vessel for creating an anastomosis that contains a cutting mechanism (306), a seal (302) that can seal the opening in the blood vessel (Figure 12F), and a tool body (28, Figure 12F) that is coupled to the cutting mechanism and contains an inner lumen (see Figure 12F) that is capable of delivering a seal (see Figure 12D). LeMole'369 does not teach that the tool body and cutting mechanism are attached. Further, LeMole'369 does not teach that the cutting mechanism is an electrode.

Nobles'319 teaches a device that contains a cutting mechanism (166) attached to a tool body (170) (Figure 21 and 23). The tool body has a lumen extending from a proximal end (towards 176) towards a distal end (towards 172) and the cutting mechanism is attached to the distal opening of the tool body (column 10, lines 48-58). It would have been obvious to one skilled in the art at the time the invention was made to modify the device taught by LeMole'369, by attaching the cutting mechanism to the distal end of the tool body, in order to provide structure to the device and provide a handle for the user while performing the cutting operation.

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LeMole'369 in view of Nobles'319 teaches the invention substantially as claimed, except that the cutting mechanism contains an electrode. Burbank'071 teaches a cutting device (102) that contains an electrode (126) because using RF energy to cut tissue is more efficient than cutting with a blade because it does not need to be frequently replaced like blades (column 2, lines 26-55). Regarding Claims 5-7, Burbank'071 teaches a metallic conductor (128) (column 5, lines 6-18) that delivers RF energy (column 4, lines 50-55) to the electrode (128) (column 5, lines 34-40). It would have been obvious to one skilled in the art at the time the invention was made to modify the cutter taught by LeMole'369 with an RF cutter taught by Burbank'071 because RF cutters do not need to be replaced because they do not get dull.

Claim 2: LeMole'369 teaches a tether (304) attached to the seal.

Claim 3: LeMole'369 teaches a shaft (36) attached to the seal.

Claim 4: LeMole'369 teaches a rod (36) attached to the seal.

Claim 9: LeMole'369 teaches that the seal is made of Mylar®, a known flexible material (column 8, lines 21-26).

Claim 11 and 12: LeMole'369 teaches a shaft (36) that is capable of delivering the seal through the tool body (28).

Claim 13 and 14: LeMole'369 teaches that the seal contains inflatable chambers (column 7, lines 58 to column 8, line 35).

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over LeMole'369 in view of Nobles'319 and Burbank'071, as applied to Claim 1, in further view of Fortune'231.

LeMole'369 in view of Nobles'319 and Burbank'071 teach the limitations of Claims 8, except for the use of a coating.

Fortune'231 teaches that the seal can have a coating because it improves adhesion of the sealing member to the vessel wall (paragraph [0045]). It would have been obvious to one skilled in the art at the time the invention was made to modify the seal taught by LeMole'369 in view of Nobles'319 and Burbank'071 with a coating taught by Fortune'231 to improve bonding of the seal with the vessel wall and improve the quality of the seal.

Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over LeMole'369 in view of Nobles'319 and Burbank'071, as applied to Claim 1, in further view of Blatter (US Patent 6,248,117).

LeMole'369 in view of Nobles'319 and Burbank'071 teach the limitations of Claims 15-17 and 27-29, except for an opening.

Blatter'117 teaches an opening (that wire 150 passes through) in the sealing member (160) in order to pass a wire for piercing the wall of a blood vessel (column 21, lines 31-43). It would have been obvious to one skilled in the art at the time the invention was made to modify the seal of LeMole'369 in view of Nobles'319 and Burbank'071 with a hole taught by Blatter'117 in order to pass a piercing wire.

Claims 10, 18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over LeMole'369 in view of Nobles'319 and Burbank'071, as applied to Claim 1, in further view of Fortune, et al. (US Patent 2004/0215231).

LeMole'369 in view of Nobles'319 and Burbank'071 teach the limitations of Claims 10, 18 and 20 except for the use of ribs in the sealing member (Claim 10), a plurality of sealing devices (Claim 18) and biodegradable sealing devices (Claim 20).

Claim 10: Fortune'231 teaches that the sealing members contain a plurality of ribs (Figure 7) so it can be folded into a delivery configuration (paragraph [0112]). It would have been obvious to one skilled in the art at the time the invention was made to modify the sealing member of LeMole'369 in view of Nobles'319 and Burbank'071 with the ribs taught by Fortune'231 so it can be folded into a delivery configuration.

Claim 18: Fortune'231 teaches a sealing device that uses a plurality of sealing members (11, 12) coupled to a delivery shaft (13) in which the sealing members are configurable into a delivery configuration (Figure 2-4) for passage into the blood vessel and a sealing configuration (Figure 5) for sealing the blood vessel. Fortune'231 teaches the use of a plurality of sealing members because they hold the plugging device in place and reduce the risk of the plug occluding the vessel that is being sealed (paragraph [0004], [0005]). It would have been obvious to one skilled in the art at the time the invention was made to modify the device of LeMole'369 in view of Nobles'319 and Burbank'071 with a plurality of sealing members taught by Fortune'231 in order to more securely attach the plugging member.

Claim 20: Fortune'231 teaches the use of biodegradable sealing devices so they can be in place long enough to seal the puncture and then disintegrate (paragraph [0009]). It would have been obvious to modify the seal of LeMole'369 in view of

Nobles'319 and Burbank'071 by making it out of a biodegradable material so the seal can disappear on its own, as taught by Fortune'231.

Claim 21, 22, 24 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over LeMole (US Patent 5,893,369) in view of Nobles'319.

Claim 21: LeMole'369 discloses a device that creates an opening in a blood vessel for creating an anastomosis that contains a cutting mechanism that contains a cutting blade (306), an inflatable seal (302) that can seal the opening in the blood vessel (Figure 12F, column 7, lines 58 to column 8, line 35), and a tool body (28, Figure 12F) that is coupled to the cutting mechanism and contains an inner lumen (see Figure 12F) that is capable of delivering a seal (see Figure 12D). LeMole'369 does not teach that the tool body and cutting mechanism are attached.

Nobles'319 teaches a device that contains a cutting mechanism (166) attached to a tool body (170) (Figure 21 and 23). The tool body has a lumen extending from a proximal end (towards 176) towards a distal end (towards 172) and the cutting mechanism is attached to the distal opening of the tool body (column 10, lines 48-58). It would have been obvious to one skilled in the art at the time the invention was made to modify the device taught by LeMole'369, by attaching the cutting mechanism to the distal end of the tool body, in order to provide structure to the device and provide a handle for the user while performing the cutting operation.

Claim 22: LeMole'369 discloses a lumen (306, 308, 310) that is coupled to the inflatable chamber.

Claim 24: LeMole'369 discloses that the seal is a made of Mylar®, a known flexible material (column 8, lines 21-26).

Claim 26: LeMole'369 discloses a shaft (36) that is capable of delivering the seal through the tool body (28).

Claims 23 and 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over LeMole'369 in view of Nobles'319, as applied to Claim 21, in further view of Fortune'231.

LeMole'369 and Nobles'319 teach the limitations of Claims 23 and 25, except for the use of a coating (Claim 23) and ribs in the sealing member (Claim 25).

Claim 23: Fortune'231 teaches that the seal can have a coating because it improves adhesion of the sealing member to the vessel wall (paragraph [0045]). It would have been obvious to one skilled in the art at the time the invention was made to modify the seal taught by LeMole'369 with a coating taught by Fortune'231 to improve bonding of the seal with the vessel wall and improve the quality of the seal.

Claim 25: Fortune'231 teaches that the sealing members contain a plurality of ribs (Figure 7) so it can be folded into a delivery configuration (paragraph [0112]). It would have been obvious to one skilled in the art at the time the invention was made to use ribs in order to aid in the placing the sealing members in a delivery configuration.

Claims 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over LeMole'369 in view of Nobles'319, as applied to Claims 21, in further view of Blatter'117.

LeMole'369 and Nobles'319 teaches the limitations of Claims 27-29, except for an opening.

Blatter'117 teaches an opening (that wire 150 passes through) in the sealing member (160) in order to pass a wire for piercing the wall of a blood vessel (column 21, lines 31-43). It would have been obvious to one skilled in the art at the time the invention was made to modify the seal taught by LeMole'369 with a hole taught by Blatter'117 in order to pass a piercing wire.

Claims 48-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over LeMole'369 in view of Nobles'319 and in further view of Fortune'231.

Claim 48 and 49: LeMole'369 teaches a device that creates an opening in a blood vessel for creating an anastomosis that contains a cutting mechanism (306), a seal (302) that can seal the opening in the blood vessel (Figure 12F), and a tool body (28, Figure 12F) that is coupled to the cutting mechanism and contains an inner lumen (see Figure 12F) that is capable of delivering a seal (see Figure 12D). LeMole'369 does not teach that the tool body and cutting mechanism are attached.

Nobles'319 teaches a device that contains a cutting mechanism (166) attached to a tool body (170) (Figure 21 and 23). The tool body has a lumen extending from a proximal end (towards 176) towards a distal end (towards 172) and the cutting mechanism is attached to the distal opening of the tool body (column 10, lines 48-58). It would have been obvious to one skilled in the art at the time the invention was made to modify the device of LeMole'369, by attaching the cutting mechanism to the distal end

of the tool body, as taught by Nobles'319, in order to provide structure to the device and provide a handle for the user while performing the cutting operation.

Further, LeMole'369 in view of Nobles'319 does not teach a plurality of seal members that are coated. Fortune'231 teaches a sealing device that uses a plurality of sealing members (11, 12) coupled to a delivery shaft (13) in which the sealing members are configurable into a delivery configuration (Figure 2-4) for passage into the blood vessel and a sealing configuration (Figure 5) for sealing the blood vessel. Fortune'231 teaches the use of a plurality of sealing members that are coated because they hold the plugging device in place and reduce the risk of the plug occluding the vessel that is being sealed (paragraph [0004], [0005]). Fortune'231 teaches that the seal can have a coating because it improves adhesion of the sealing member to the vessel wall (paragraph [0045]). It would have been obvious to one skilled in the art at the time the invention was made to modify the device of LeMole'369 in view of Nobles'319, with a plurality of sealing members as taught by Fortune'231 in order to more securely attach the plugging member.

Claim 50: Fortune'231 teaches that the seal is made of a flexible material (paragraph [0019]) because it allows the seal to be put into a delivery configuration (paragraph [0023]). It would have been obvious to one skilled in the art at the time the invention was made to make the seals taught by Fortune'231 flexible so they can be delivered to a puncture.

Claim 51: Fortune'231 teaches that the sealing members contain a plurality of ribs (Figure 7) so it can be folded into a delivery configuration (paragraph [0112]). It

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would have been obvious to one skilled in the art at the time the invention was made to use ribs in order to aid in the placing the sealing members in a delivery configuration.

Claims 52, 53, 54, 57: Fortune'231 teaches that the sealing members contain an opening (opening that accommodates element 13) in order to be delivered. Further, this opening can allow the delivery of an additional sealing plug (paragraph [0112]) or a suture. It would have been obvious to one skilled in the art at the time the invention was made to have an additional opening to accommodate a delivery apparatus and/or a sealing plug.

Claim 55: Fortune'231 teaches that the sealing members are stacked when in a delivery configuration (Figure 2) in order to accommodate the sealing members in a delivery tube. It would have been obvious to one skilled in the art at the time the invention was made to stack the sealing members order to accommodate the delivery configuration of the sealing members.

Claim 56: Fortune'231 teaches that the sealing configuration comprises the seal members to be fanned out (Figures, 3, 5) in order to cover the puncture being sealed.

Response to Arguments

Applicant argues that the tool body is not coupled to the cutting mechanism in LeMole'369. This is not persuasive because it is clear from the figures that the the two devices are linked together, via, for example, element 30 in Figures 12d, 12e. However, in light of Applicant's amendment, the two devices are not explicitly connected. However, this argument is moot in view of the new grounds of rejection.

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Regarding Applicant's arguments that the seal openings are not disclosed for use in passing agents in Claims 15-17 and 27-29, this is not persuasive because the seals contain openings that are capable of passing agents.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lindsey Bachman whose telephone number is 571-272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm, and alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, LoAn Thanh can be reached on 571-272-4966. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

lb



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